

### **REMARKS**

Applicants thank the Examiner for the thorough consideration given the present application.

#### **Status of the Claims**

Claims 5, 7, 9-11, and 13 will be pending in the above-identified application upon entry of the present amendment. Claim 5 has been amended. Claim 8 has been cancelled herein. Claim 13 has been added. Support for the recitations in claim 5 and new claim 13 can be found in Test Example 1 of the present specification. Therefore, no new matter has been added. Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

#### **Statement of the Substance of the Interview**

Applicants would like to thank the Examiner for her time during the interview on March 18, 2009. Applicants appreciate the courtesies extended to them in this application. In compliance with MPEP 713.04, Applicants submit the following remarks.

The Interview Summary sufficiently summarizes the discussions during the interview. Although an agreement could not be reached, Applicants believe that the claims are now in condition for allowance. Should the Examiner believe that there remains any outstanding issues, Applicants respectfully request that the Examiner contact Applicants' Representative so as to expedite resolution of these outstanding issues, via an Examiner's Amendment or the like.

**Issues under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 5 and 7-11 under 35 U.S.C. § 103(a) as being obvious over Ueda '103 (US 6,831,103) in view of Hamilton (J. Neurol. Neurosurg Psychiat, 1960, 23, 56). Applicants respectfully traverse. Reconsideration and withdrawal of this rejection are respectfully requested based on the following considerations.

**Legal Standard for Determining Prima Facie Obviousness**

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Exemplary rationales that may support a conclusion of obviousness include:

- (a) combining prior art elements according to known methods to yield predictable results;

- (b) simple substitution of one known element for another to obtain predictable results;
- (c) use of known technique to improve similar devices (methods, or products) in the same way;
- (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP 2143.03.

*Distinctions over the Cited References*

The present invention is directed to a method for treating an individual with a mood disorder having at least one of a group of specific symptoms comprising administering an effective amount of a composition comprising theanine to the individual in need thereof, wherein said mood disorders are distinct from mood disorders associated with menstruation and the individual is a normofolatemetic patient, as recited in claim 5.

Although the relationship between lack of folate and depression may be known, as amended, the present invention is directed to cases where theanine is administered to an individual with at least one symptom selected from the group consisting of feelings of guilt,

suicide, and retardation: psychomotor (according to the assessment by the Hamilton scale) and whose folate level is normal. This element is not disclosed by either Ueda et al. '103 or Hamilton.

Furthermore, the Examiner admits that Ueda et al. '103 do not teach that the mood is assessed by the Hamilton scale and also do not teach the different types of mood listed in claims 9-11. The Examiner attempts to overcome this deficiency by alleging that Hamilton teaches a rating scale for measuring symptoms such as feelings of guilt, suicide, and retardation: psychomotor. However, neither Ueda et al. '103 nor Hamilton teaches that these specific symptoms can be treated by administering an effective amount of a composition comprising theanine. In other words, Ueda et al. '103 disclose specific symptoms that can be treated with theanine, but the Examiner cannot rely on Hamilton to expand the symptoms that can be treated since Hamilton only discloses a rating scale for measuring symptoms. As stated in *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007), "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Ueda et al. '103 in view of Hamilton fail to disclose all of the claim limitations of independent claim 5, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious. Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and

withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

### **CONCLUSION**

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 5, 7, 9-11, and 13 are allowed and patentable under the provisions of title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Reg. No. 58,258 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By



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